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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/549,590	09/20/2005	Takao Sato	930055-2035	1130

7590 03/17/2008  
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EXAMINER
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HELM, CARALYNNE E

ART UNIT	PAPER NUMBER
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1615

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,590	<b>Applicant(s)</b> SATO ET AL.	
	<b>Examiner</b> CARALYNNE HELM	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/16/07, 7/18/07</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "at least one member selected from..." does not distinctly define the group from which the selection is being made. Thus it is unclear whether the selection options are phosphate group-containing methacrylates represented by structural formula I only or if the selections options are phosphate group-containing methacrylates represented by structural formula I, monomers having a nitrogen atom in its side chain, and monomers copolymerizable with these components. For the sake of applying prior art, the examiner has taken the latter interpretation.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 8-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Dobrozsi et al. (U.S. Patent No. 6,503,955).

Dobrozsi et al. teach a solution with a polyoxyalkylene copolymer of ethylene oxide with propylene oxide (poloxamer/pluronic) and propylene glycol, in the absence of an ionic compound (see column 5 lines 37-63 and example XIII vehicle formulation; instant claims 8-10). Therefore claims 8-10 are unpatentable over Dobrozsi et al.

Claims 1, 3, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Wichterle et al. (U.S. Patent No. 3,220,960 – listed as Drahoslav Lim et al. on 1449).

Wichterle et al. disclose a molded gel (ophthalmic lens) made of a copolymer of acrylamide (monomers having a nitrogen atom in its side chain) at 15%, ethylene glycol monomethacrylate (hydrophilic monomer having a hydroxyl group in its molecule) and ethylene glycol dimethacrylate (monomer copolymerizable with the other monomers) (see column 5 lines 61-70; instant claims 1 and 3-4). Further, Wichterle et al. teach that the resulting gel is loaded with penicillin (cationic group containing drug with tertiary amine) (see column 5 lines 760-73; instant claim 1). Therefore claims 1, 3, 4, and 5 are unpatentable over Wichterle et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of *Graham v. John Deere Co.* have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sulc et al. (U.S. Patent No. 5,270,415) in view of Aiache et al. (U.S. Patent No. 6,713,080).

Sulc et al. teach a contact lens as a drug delivery system where a cationic and anionic monomer pair is used (see column 5 lines 3-6; instant claim 6). Specifically Sulc et al. teach the lens made from a copolymer of N,N-dimethylaminoethyl methacrylate (anionic monomer) methacrylic acid (cationic monomer), 2-hydroxyethyl methacrylate (hydrophilic monomer) and ethylene glycol dimethacrylate (monomer copolymerizable with the other monomers) (see column 2 lines 66-67, column 3 lines 3-6 and 58-61, column 4 lines 22-25, and example 1;

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instant claim 6). Sulc et al. teach the anionic to cationic polymer ratio in one embodiment to be approximately 90 mol% (92 mol% as calculated by examiner from example 17). It would therefore have been obvious to one of ordinary skill in the art at the time of the invention to use the contact lens formulation of Sulc et al. with an anion-cationic monomer ratio of 90mol%. Sulc et al. do not teach particular drugs to use in the embodiment where the lens is also a drug delivery device.

Aiache et al. teach the inclusion of a sodium diclofenac, an anionic and carbonyl group containing drug, in a poly(2-hydroxyethyl methacrylate) hydrogel contact lens (see example 7; instant claims 6 and 7). Thus in view of the teachings of Aiache et al. it would have been obvious to one of ordinary skill in the art at the time of the invention to employ sodium diclofenac in the invention of Sulc et al. Thus claims 6 and 7 are obvious over Sulc et al. in view of Aiache et al.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamae et al. (Makromolekulare Chemie-Macromolecular Chemistry and Physics 1992 193:983-990) in view of Janda et al. (U.S. Patent No. 4,640,936) and Aiache et al.

Nakamae et al. teach the use of phosphate containing monomers in conjunction with hydrophilic monomers in copolymers used in hydrogels for drug delivery (page 983 paragraph 1 lines 1-6, paragraph 3 and page 984 paragraphs 2-4; instant claim 1) Specifically, Nakamae et al. teach N,N-dimethacrylamide, acrylic acid and 2-hydroxy ethylmethacrylate as the hydrophilic monomers and 2-methacryloyloxyethyl dihydrogen phosphate (structure of formula I and II) as the phosphate containing monomer (see page 984 paragraphs 2 and 3; instant claim 1). Nakamae et al. do not specifically teach the use a structure of formula II or a particular drug to incorporate. However, Janda et al. teach the use of both 2-methacryloyloxyethyl dihydrogen

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phosphate and bis-(methacryloyloxyethyl) hydrogen phosphate (formula III) in a polymeric preparation for biological use (see claim 1; instant claim 2). It would therefore have been obvious to one of ordinary skill in the art at the time of the invention to use any phosphate containing monomers, particularly those of similar structure, known at the time as suitable in biological applications within the preparation taught by Nakamae et al. Further, Aiache et al. teach the inclusion of a sodium diclofenac, an anionic and carbonyl group containing drug, in poly(2-hydroxyethyl methacrylate) contact lens hydrogel (see example 7; instant claims 6 and 7). Thus in view of the teachings of Aiache et al. it would have been obvious to one of ordinary skill in the art at the time of the invention to employ sodium diclofenac in the invention of Janda et al. modified invention of Nakamae et al. Thus, claims 6 and 7 are obvious over Nakamae et al. in view of Janda et al. and Aiache et al.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/  
Examiner, Art Unit 1615

/Michael P Woodward/  
Supervisory Patent Examiner, Art Unit  
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